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Case No. 10709/47

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Zheng Wei	
Serial No:	10/630,180	Examiner: DeBerry, Regina M.
Filed:	July 30, 2003	Group Art Unit: 1647

For: METHOD FOR MULTIPLE CHEMOKINE RECEPTOR SCREENING FOR ANTAGONISTS USING RAM ASSAY

PRELIMINARY AMENDMENT

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
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Dear Sir:

Applicant thanks Examiners DeBerry and Allen for the courteous and helpful discussion of this case with the undersigned on October 11, 2007.

Before examination on the merits, please enter the following amendments. Submitted herewith is a Request for Continued Examination pursuant to 37 CFR § 1.114.

Amendments to the Claims are reflected in the listing of claims which begins at page 2 of this paper.

Claim Status begins at page 13 of this paper.

Substance of Interview is at page 14.

Remarks/Arguments begin on page 15 of this paper.

Amendments to the Claims:

Claims 55-60 were previously cancelled. Please cancel claims 27, 54, 63 and 64. Please amend claims 1, 4-10, 13, 16, 28, 31-37, 40, 43, 46, 47, 61 and 62 (the changes in these claims are shown with ~~strikethroughs~~ for deleted matter and underlining for added matter). Please add new claims 65-70. A complete listing of the claims is listed below with the proper claim identifiers; this listing of claims will replace all prior versions, and listings, of claims in the application:

1 (Currently amended) A method for identifying ~~a~~ an antagonist of at least one of selected first and second chemoattractant receptors ~~antagonist~~, comprising:

providing an apparatus comprising an upper chamber and a lower chamber separated by a porous membrane;

placing a candidate antagonist and a cell population comprising the first and second selected chemoattractant receptors in the upper chamber;

placing an inhibitory concentration of a ligand for the first selected chemoattractant receptor in the lower chamber;

placing an inhibitory concentration of a ligand for the second selected chemoattractant receptor in the lower chamber; and

monitoring movement of the cell population from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of at least one of the first and second selected chemoattractant receptors~~; and~~

~~determining whether an identified antagonist is an antagonist for one of the first chemoattractant receptors, the second chemoattractant receptor, or both~~.

2. (Previously presented) The method of claim 1, wherein at least two candidate antagonists are placed with the cell population in the upper chamber.

3. (Original) The method of claim 1, wherein the candidate antagonist is a peptide, peptide-like molecule, non-peptidyl organic compound, inorganic compound, nucleic acid or antibody.

4. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 50% of maximal ligand-activated cell migration.

5. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 95% of maximal ligand-activated cell migration.

6. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 100% of maximal ligand-activated cell migration.

7. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits cell migration greater than or equal to about 50% of maximal ligand-activated cell migration.

8. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits cell migration greater than or equal to about 95% of maximal ligand-activated cell migration.

9. (Currently amended) The method of claim 1, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits

cell migration greater than or equal to about 100% of maximal ligand-activated cell migration.

10. (Currently amended) The method of claim 1, wherein the selected first and second chemoattractant receptors are each independently a chemokine receptor.

11. (Original) The method of claim 10, wherein the chemokine receptor is selected from the group consisting of CCR, CXCR, CX3CR, and XCR classes of chemokine receptors.

12. (Original) The method of claim 11, wherein the chemokine receptors are CXCR1, CXCR2, CXCR3, CXCR4, CXCR5, CCR1, CCR2, CCR3, CCR4, CCR5, CCR6, CCR7, CCR8, CCR9, CCR10, CCR11, CX3CR1 or XCR1.

13. (Currently amended) The method of claim 1, wherein the ligand for the first selected chemoattractant receptor is a chemokine.

14. (Previously presented) The method of claim 13, wherein the chemokine is selected from the group consisting of CCR, CXCR, and CX3CR receptor ligands.

15. (Original) The method of claim 14, wherein the chemokine is IL-8, GCP-2, Gro α, Gro β, Gro γ, ENA-78, PBP, MIG, IP-10, I-TAC, SDF-1α, BLC, MIP-1α, MIP-1β, RANTES, HCC-1, HCC-2, HCC-3, HCC-4, MCP-1, MCP-2, MCP-3, MCP-4, eotaxin-1, eotaxin-2, TARC, MDC, MIP-3α, MIP-3β, 6Ckine, I-309, TECK, lymphotactin, fractalkine, TCA-4, Exodus-2, Exodus-3, or CKβ-11.

16. (Currently amended) The method of claim 1, wherein the ligand for the second selected chemoattractant receptor is a chemokine.

17. (Previously presented) The method of claim 16, wherein the chemokine is selected from the group consisting of CCR, CXCR, and CX3CR receptor ligands.

18. (Original) The method of claim 17, wherein the chemokine is IL-8, GCP-2, Gro α, Gro β, Gro γ, ENA-78, PBP, MIG, IP-10, I-TAC, SDF-1α, BLC, MIP-1α, MIP-1β, RANTES, HCC-1, HCC-2, HCC-3, HCC-4, MCP-1, MCP-2, MCP-3, MCP-4, eotaxin-1, eotaxin-2, TARC, MDC, MIP-3α, MIP-3β, 6Ckine, I-309, TECK, lymphotactin, fractalkine, TCA-4, Exodus-2, Exodus-3, or CKβ-11.

19. (Previously presented) The method of claim 1, wherein the ligands for the first and the second chemokine receptors are placed in the lower chamber simultaneously.

20. (Previously presented) The method of claim 1, wherein the ligands for the first and the second chemokine receptors are placed in the lower chamber in series.

21. (Previously presented) The method of claim 1, wherein the candidate antagonist is placed before at least one of the ligands.

22. (Previously presented) The method of claim 1, wherein monitoring movement comprises measuring a signal.

23. (Original) The method of claim 22, wherein the signal is a fluorescent signal.

24. (Previously presented) The method of claim 1, wherein monitoring movement comprises counting cells using a microscope.

25. (Previously presented) The method of claim 1, wherein monitoring movement comprises labeling cells with a marker.

26. (Original) The method of claim 25, wherein the marker is a dye or a radioactive label.

27. (Cancelled)

28. (Currently amended) A method for identifying a an antagonist of at least one of selected first and second chemoattractant receptors ~~antagonist~~, comprising:

providing an apparatus comprising an upper chamber and a lower chamber separated by a porous membrane;

placing a candidate antagonist and a first cell population and a second cell population in the upper chamber, wherein the first cell population comprises a the first selected chemoattractant receptor and wherein the second cell population comprises a the second selected chemoattractant receptor;

placing an inhibitory concentration of a ligand for the first selected chemoattractant receptor in the lower chamber;

placing an inhibitory concentration of a ligand for the second selected chemoattractant receptor in the lower chamber; and

monitoring movement of the first and the second cell populations from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of at least one of the first and second selected chemoattractant receptors~~; and~~

~~determining whether an identified antagonist is an antagonist for one of the first chemoattractant receptors, the second chemoattractant receptor, or both~~.

29. (Previously presented) The method of claim 28, wherein at least two candidate antagonists are placed with the first and the second cell populations in the upper chamber.

30. (Original) The method of claim 28, wherein the candidate antagonist is a peptide, peptide-like molecule, non-peptidyl organic compound, inorganic compound, nucleic acid or antibody.

31. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 50% of maximal ligand-activated cell migration.

32. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 95% of maximal ligand-activated cell migration.

33. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the first selected chemoattractant receptor inhibits cell migration greater than or equal to about 100% of maximal ligand-activated cell migration.

34. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits cell migration greater than or equal to about 50% of maximal ligand-activated cell migration.

35. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits cell migration greater than or equal to about 95% of maximal ligand-activated cell migration.

36. (Currently amended) The method of claim 28, wherein the inhibitory concentration of the ligand for the second selected chemoattractant receptor inhibits cell migration greater than or equal to about 100% of maximal ligand-activated cell migration.

37. (Currently amended) The method of claim 28, wherein the first and second selected chemoattractant receptors are each independently a chemokine receptor.

38. (Original) The method of claim 37, wherein the chemokine receptor is selected from the group consisting of CCR, CXCR, CX3CR, and XCR classes of chemokine receptors.

39. (Original) The method of claim 38, wherein the chemokine receptors are CXCR1, CXCR2, CXCR3, CXCR4, CXCR5, CCR1, CCR2, CCR3, CCR4, CCR5, CCR6, CCR7, CCR8, CCR9, CCR10, CCR11, CX3CR1 or XCR1.

40. (Currently amended) The method of claim 28, wherein the ligand for the first selected chemoattractant receptor is a chemokine.

41. (Previously presented) The method of claim 40, wherein the chemokine is selected from the group consisting of CCR, CXCR, and CX3CR receptor ligands.

42. (Original) The method of claim 41, wherein the chemokine is IL-8, GCP-2, Gro α, Gro β, Gro γ, ENA-78, PBP, MIG, IP-10, I-TAC, SDF-1α, BLC, MIP-1α, MIP-1β, RANTES, HCC-1, HCC-2, HCC-3, HCC-4, MCP-1, MCP-2, MCP-3, MCP-4, eotaxin-1, eotaxin-2, TARC, MDC, MIP-3α, MIP-3β, 6Ckine, I-309, TECK, lymphotactin, fractalkine, TCA-4, Exodus-2, Exodus-3, or CKβ-11.

43. (Currently amended) The method of claim 28, wherein the ligand for the second selected chemoattractant receptor is a chemokine.

44. (Previously presented) The method of claim 43, wherein the chemokine is selected from the group consisting of CCR, CXCR, and CX3CR receptor ligands.

45. (Original) The method of claim 44, wherein the chemokine is IL-8, GCP-2, Gro α, Gro β, Gro γ, ENA-78, PBP, MIG, IP-10, I-TAC, SDF-1α, BLC, MIP-1α, MIP-1β, RANTES, HCC-1, HCC-2, HCC-3, HCC-4, MCP-1, MCP-2, MCP-3, MCP-4, eotaxin-1, eotaxin-2, TARC, MDC, MIP-3α, MIP-3β, 6Ckine, I-309, TECK, lymphotactin, fractalkine, TCA-4, Exodus-2, Exodus-3, or CKβ-11.

46. (Currently amended) The method of claim 28, wherein the ligands for the first and the second selected chemoattractant receptor are placed in the lower chamber simultaneously.

47. (Currently amended) The method of claim 28, wherein the ligands for the first and the second selected chemoattractant receptor are placed in the lower chamber in series.

48. (Previously presented) The method of claim 28, wherein the at least one candidate antagonist is placed in the apparatus before the at least one of the ligands.

49. (Previously presented) The method of claim 28, wherein the monitoring movement comprises measuring a signal.

50. (Original) The method of claim 49, wherein the signal is a fluorescent signal.

51. (Previously presented) The method of claim 28, wherein monitoring movement comprises counting cells using a microscope.

52. (Previously presented) The method of claim 28, wherein monitoring movement comprises labeling cells with a marker.

53. (Original) The method of claim 52, wherein the marker is a dye or a radioactive label.

54-60 (Cancelled)

61. (Currently amended) The method of claim 1, wherein the first and second selected chemoattractant receptors are ~~chemoattractant receptor is~~ selected from the group consisting of C5aR, FPRL1 receptor, CXCR4, CXCR3, CCR1, and CCR9.

62. (Currently amended) The method of claim 28, wherein first and second selected chemoattractant receptors are ~~chemoattractant receptor is~~ selected from the group consisting of C5aR, FPRL1 receptor, CXCR4, CXCR3, CCR1, and CCR9.

63. (Cancelled)

64. (Cancelled)

65. (New) The method of claim 1, further comprising a step of determining whether an identified antagonist is an antagonist for one of the first selected chemoattractant receptors, the second selected chemoattractant receptor, or both.

66. (New) The method of claim 65, wherein determining is performed by a method comprising the steps of:

a) determining whether the identified antagonist is the antagonist for the first selected chemoattractant receptor comprising the steps of:

i) placing a first cell population comprising the first selected chemoattractant receptor with a candidate antagonist in the upper chamber,

ii) placing an inhibitory concentration of a ligand for the first selected chemoattractant receptor in the lower chamber, and

iii) assaying movement of the first cell population from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of the first selected selected chemoattractant receptor; and

b) determining whether the identified antagonist is the antagonist for the second selected chemoattractant receptor comprising the steps of:

i) placing a second cell population comprising the second selected chemoattractant receptor with the candidate antagonist in the upper chamber,

ii) placing an inhibitory concentration of a ligand for the second selected chemoattractant receptor in the lower chamber, and

iii) assaying movement of the second cell population from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of the second selected chemoattractant receptor.

67. (New) The method of claim 65, wherein determining is performed by calcium mobilization assay or cell migration assay.

68. (New) The method of claim 28, further comprising a step of determining whether an identified antagonist is an antagonist for one of the first selected chemoattractant receptors, the second selected chemoattractant receptor, or both.

69. (New) The method of claim 68, wherein determining is performed by a method comprising the steps of:

a) determining whether the identified antagonist is the antagonist for the first selected chemoattractant receptor comprising the steps of:

i) placing a first cell population comprising the first selected chemoattractant receptor and a candidate antagonist in the upper chamber,

ii) placing an inhibitory concentration of a ligand for the first selected chemoattractant receptor in the lower chamber, and

iii) monitoring movement of the first cell population from the upper chamber to the lower chamber, wherein the movement identifies the

candidate antagonist as an antagonist of the first selected chemoattractant receptor; and

b) determining whether the identified antagonist is the antagonist for the second selected chemoattractant receptor comprising the steps of:

i) placing a second cell population comprising the second selected chemoattractant receptor and the candidate antagonist in the upper chamber,

ii) placing an inhibitory concentration of a ligand for the second selected chemoattractant receptor in the lower chamber, and

iii) monitoring movement of the second cell population from the upper chamber to the lower chamber, wherein the movement identifies the candidate antagonist as an antagonist of the second selected chemoattractant receptor.

70. (New) The method of claim 68, wherein determining is performed by calcium mobilization assay or cell migration assay.

CLAIM STATUS

Claims 55-60 were previously cancelled. Claims 27, 54, 63 and 64 are currently cancelled. Claims 1, 4-10, 13, 16, 28, 31-37, 40, 43, 46, 47, 61 and 62 are amended Support for amendments to claims 1 and 28 may be found throughout the specification including, for example, at page 19, lines 11-15; page 27, lines 18-23; and Example 9. Claims 4-10, 13, 16, 28, 31-37, 40, 43, 46, 47, 61 and 62 were amended for clarity.

Please add new claims 65-70.

Support for new claims 65-70 may be found throughout the specification, including at the following locations:

Claims 65 and 68, see *e.g.*, specification at page 25, lines 1-14, especially lines 12-14;

Claims 66 and 69, see *e.g.*, specification at page 20, lines 10-13 and 28-3; pages 16-18; and

Claims 67 and 70, see *e.g.*, specification at page 25, lines 1-14.

No new matter has been added.

Claims 1-26, 28-53 and 61, 62, and 65-70 are pending.

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicant thanks Examiners DeBerry and Allen for the courteous and helpful telephonic discussion of this case with the undersigned on October 11, 2007. In this interview, all pending claims 1-53 and 61-64 were discussed, with particular emphasis on independent claims 1 and 28. Applicant also thanks the Examiners for reviewing and commenting on "Draft Claims" sent via facsimile on October 9, 2007.

During the telephonic discussion, the undersigned emphasized that independent claims 1 and 28 comply with the enablement requirement. The Examiners pointed out that Applicant's claim 1 is not enabled because the disclosure of the specification can not be read into the claim.

The undersigned agreed to consider further claim amendments to overcome the enablement rejection.

The undersigned notes that the claim amendments submitted herein are different than those previously facsimiled to the Examiner. Applicant believes that current amendments address the Examiner's remaining concerns.

REMARKS RELATING TO THE FINAL OFFICE ACTION DATED AUGUST 14, 2007

35 U.S.C. § 112, First Paragraph – Enablement Rejection

The Examiner previously rejected claims 1-54, 61 and 62 under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement because the claims contain subject matter was not described in the specification in such a way as to enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner contended that the instant claims are not enabled because the specification fails to teach how to identify an unknown candidate antagonist as true antagonist and its chemoattractant receptor following the BiRAM and MultiRAM assays, and as such a large quantity of experimentation would be necessary to identify a candidate antagonist as a true antagonist and its chemoattractant receptor.

Applicant disagrees with the Examiner.

Nonetheless, Applicant cancelled claims 27 and 54. In view of the cancellation, the § 112, First Paragraph rejection of claims 27 and 54 is moot.

Applicant also amended independent claims 1 and 28. As amended, claims 1 and 28 are generally directed to methods for identifying an antagonist of at least one of selected first and second chemoattractant receptors comprising providing an apparatus comprising an upper chamber and a lower chamber separated by a porous membrane; placing in the upper chamber a candidate antagonist and either 1) a single cell population comprising two (i.e., first and second) selected chemoattractant receptors (as in claim 1), or 2) two cell populations (i.e., a first cell population and a second cell population), wherein the first cell population comprises the first selected chemoattractant receptor and wherein the second cell population comprises the second selected chemoattractant receptor (as in claim 28); placing an inhibitory concentration of a ligand for the first selected chemoattractant receptor in the lower chamber; placing an inhibitory concentration of a ligand for the second selected chemoattractant receptor in the lower chamber; and monitoring movement of the cell population(s) from the upper chamber to the lower chamber, wherein the movement

identifies the candidate antagonist as an antagonist of at least one of the first and second selected chemoattractant receptors.

Applicant asserts that the specification fully enables the scope of the claims 1 and 28 and any claims dependent thereon for the following reasons.

Throughout the specification, Applicant provides ample description of BiRAM and MutiRAM assays for use in identifying non-specific candidate antagonist hits to the chemoattractant receptors selected for use in the assays. See instant specification at pages 18 through 21, first paragraph for BiRAM assay; and pages 21, second paragraph, through page 22, lines 1-4 for MultiRAM assay. Moreover, Applicant further provides, for instance, at pages 39-43 specific examples (Examples 8, 9 and 10) of BiRAM screening assay. As such, a skilled artisan, provided the guidance in the specification, would understand how to use BiRAM and MultiRAM assays to identify antagonist hits to the selected chemoattractant receptors used in those assays. Applicant points out that, as amended, claims 1 and 28 do not require that the identity of the chemoattractant receptor reacting in the BiRAM or MultiRAM assay is known at the end of the BiRAM and MultiRAM assays.

As taught by the Applicant and as defined by new claims 65-70, the identity of the chemoattractant receptor(s) reacting in the BiRAM and MultiRAM assays may be determined, if so desired, using several methods known in the art. Specifically, these methods allow for discriminating true chemoattractant receptor antagonist hits from the non-specific blockers following the BiRAM and MultiRAM assays (specification at page 25, lines 1-14). These methods include, for example, the RAM assay (specification at page 20, 1st full paragraph, page 22, lines 1-4, and Figs 8 and 9; and U.S. Pat. No. 7,282,338), conventional HTS methods, such as FLIPR™ that measure calcium mobilization, or a cell migration assay (chemotaxis assay) (specification at page 25, lines 1-14), among other known methods.

Particularly in view of the claim amendments and aforementioned recital of guidance found in the specification of specific assay methods that can be used to identify candidate antagonists hits of chemoattractant receptors selected for use in the assays, and the fact of actual examples, Applicant respectfully submits that the enablement rejection of claims 1-54, 61, and 62 should be withdrawn.

35 U.S.C. § 112, First Paragraph – Written Description Rejection (New Matter)

The Examiner rejected claims 27 and 54 under 35 U.S.C. § 112, First Paragraph, as failing to comply with the written description requirement.

Applicant disagrees. Nonetheless, Applicant cancelled claims 27 and 54. In view of the cancellation, the 35 U.S.C. § 112, First Paragraph of claims 27 and 54 is moot.

With respect to new claims 66 and 69, Applicant submits that the instant specification satisfies the written description requirement because it would be clear to one skilled in the art that Applicant possessed the subject matter of new claims 66 and 69 at the time of filing the instant application.

At the outset, Applicant points out that new claims 66 and 69 are generally directed to and include method steps of a RAM assay where the identity of the chemoattractant receptor reacting in the BiRAM or MultiRAM assays is determined by separately re-screening each receptor (i.e., re-screening first and second chemoattractant receptors) used in the BiRAM or MultiRAM assays by applying only one chemokine at a time.

Turning to the specification, Applicant discloses, for example at page 20, lines 10-13 and 28-30 of the specification as originally filed, that RAM assay may be used to re-screen the chemoattractant receptors used in the BiRAM assay. The steps of the RAM assay are clearly described, for example at pages 16-18. Applicant submits that description of the RAM assay with all its method steps provides sufficient support for the new claims 66 and 69.

Applicant respectfully requests the written description rejection of claims 27 and 54 be withdrawn. Applicant also requests that the written description rejection not be applied against new claims 66 and 69.

35 U.S.C. § 112, Second Paragraph - Indefiniteness

The Examiner rejected claims 27, 63 and 64 under 35 U.S.C. § 112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant disagrees. Nonetheless, Applicant cancelled claims 27, 63 and 64 and in view of the cancellation, the 35 U.S.C. § 112, Second Paragraph, as being indefinite is moot.

Applicant points out that new claim 66 is definite because the claim clearly states that a first cell population (as in claim 66) comprises the first selected chemoattractant receptor (as introduced in claim 1); and a second cell population (as in claim 66) comprises the second chemoattractant receptor (as introduced in claim 1). As such, it is clear that, although the two chemoattractant receptors for use in the BiRAM assay were expressed in a single cell population, for re-screening purposes, the two chemoattractant receptors are expressed in two separate cell populations. Accordingly, the 35 U.S.C. § 112, Second Paragraph rejection should not be applied against new claim 66.

Applicant also asserts that new claim 67 and 70 (which correspond to previous claims 63 and 64, respectively) do not include the trademark/trade name FLIPER™, and as such the 35 U.S.C. § 112, Second Paragraph rejection should not be applied against new claims 67 and 70.

CONCLUSION

Applicant respectfully submits that present application is now in condition for allowance. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

Dated: October 31, 2007

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